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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/232,290	01/15/1999	ANDREAS PLUCKTHUN	MORPHO/7	1987

7590 05/31/2002  
JAMES P HALEY JR  
FISH & NEAVE  
1251 AVENUE OF THE AMERICAS  
NEW YORK, NY 100201104

EXAMINER
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DECLoux, AMY M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 05/31/2002

26

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/232,290

Applicant(s)

PLUCKTHUN ET AL.

Examiner

Amy M. DeCloux

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-11 and 13-27 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 January 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Applicant's amendment filed 1-22-02 (Paper No. 24) is acknowledged and has been entered in part.

Claims 1-5 and 7-27 are pending.

The newly added Abstract is acceptable.

### ***Drawings***

Formal drawings and/or photographs have been submitted which fail to comply with 37 CFR 1.84. Please see the form PTO-948 enclosed with Paper No.18, mailed 12-5-00.

As of May 3, 2001, examiners may not permit corrections to drawings to be held in abeyance. Applicant must submit proposed drawing corrections in response to the instant office action.

### **INFORMATION ON HOW TO EFFECT DRAWING CHANGES**

#### **A). Correction of Informalities -- 37 CFR 1.85**

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

#### **B) Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

#### **Timing of Corrections**

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Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDONMENT of the application

### *Specification*

The substitute specification filed 1-22-02 has not been entered because it does not conform to 37 CFR 1.125(b) because: the statement as to the lack of new matter under 37 CFR 1.125(b) is missing, and a marked up copy of the substitute specification has not been supplied (in addition to the clean copy). Since the substitute specification filed by applicant 1-22-02 has not been entered, the objection to the specification is maintained.

MAINTAINED The disclosure is objected to because of the following informalities:

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

### **Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or  
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)

(e) BACKGROUND OF THE INVENTION.

(1) Field of the Invention.

(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) BRIEF SUMMARY OF THE INVENTION.

(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(h) DETAILED DESCRIPTION OF THE INVENTION.

(i) CLAIM OR CLAIMS (commencing on a separate sheet).

(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***


4. In view of applicant's amendment and Remarks, the outstanding 112 second paragraph rejections have been withdrawn.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. MAINTAINED Claims 1-5, 7-11, 13-17, and 26-27 stand rejected under 35 U.S.C. 102(b) as being anticipated by Johnson et al (WO 92/01787)(IDS). 

***Response to Arguments***

Applicant traverses the rejection. Applicant acknowledges that the instant claims encompass modified scFv fragments and states that claim 1 is limited to DNA sequences comprising modified interfaces which exist within a light chain or within a heavy chain. Applicant further states that it is unclear to the applicant why the examiner continues to contend that the claims encompass DNA sequences comprising modified interfaces between immunoglobulin domains derived from different chains

The problem the examiner is having is that it is not clear how the limitation recited in part (a) of claim 1 that "said exposed interface allows contact along a longitudinal axis between adjacent domains within a heavy or within a light chain of a larger antibody fragment or full antibody", is consistent with the claims encompassing a modified scFv. An scFv molecule consists of a heavy V domain, a linker and a light V domain, as illustrated by applicant's attachment to the instant amendment. The instant specification discloses on page 3 that the heavy chain contains four domains (one variable and three constant domains) that are adjacent along the longitudinal axis, and the light chain contains two domains (one variable and one constant domain) that are adjacent along the longitudinal axis. It is not clear to the examiner from the one disclosed working example in the instant specification of DNA encoding a modified scFv molecule, what the longitudinal axis within a heavy chain or within a light chain is, given that the scFv molecule only consists of two domains (a heavy V domain and a light V domain). Therefore, it appears that the claims encompass DNA sequences comprising modified interfaces which exist between immunoglobulin domains derived from different chains (i.e. between V domain from the heavy chain and V domain from the light chain). Applicant argues

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VL-C

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in the remarks section of the instant amendment that a scFv molecule may be engineered to comprise a modified interface between VL and VH (as recited in the Johnson reference (used in the art rejections)) or alternatively may comprise a modified interface within VL or within VH (as recited in the pending claims). Because applicant contends that the instant claims encompass scFv molecules, and because scFv molecules which comprise only two immunoglobulin domains each derived from different chains (i.e. between VH from the heavy chain and VL from the light chain) , then Johnson reads on the instant claims.

There fore though applicant's arguments have been carefully considered, they are not persuasive and the rejection is maintained, essentially for the reasons of record.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

MAINTAINED Claims 1-5, 7, 10-11, 13-27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al (WO 92/01787)(IDS) in view of Jenkins et al (PNAS 92:6057-6061, 1995)(IDS) and Knappik et al (Biotechniques 17(4):754-761, 1994) and Dubel et al. (J. Of Immunological Methods 178:201-209, 1995) and Kostelny et al (Journal of Immunology 148:1547-1553, 1992).

***Response to Arguments***

Applicant traverse the rejection on the grounds that Johnson does not teach the applicant's instant invention, and that the secondary references do nothing to make up for the lack of Johnson's teaching regarding the instant invention. However, the examiner contends that Johnson does teach applicant's invention as discussed supra, and therefore the 103 rejection is maintained essentially for the reasons of record.

***Allowable Subject Matter***

Claim 12 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period



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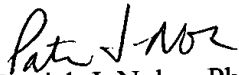
will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, PhD  
Patent Examiner, Group 1600  
May 30, 2002

  
Patrick J. Nolan, PhD  
Primary Patent Examiner, Group 1600